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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,536

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Tim Carroll

DAIRY88.007APC

4719

20995

7590

05/15/2009

Knobbe Martens Olson & Bear LLP

2040 MAIN STREET

FOURTEENTH FLOOR

IRVINE, CA 92614

EXAMINER

WOMACK, DOMINIQUE A

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

05/15/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/530,536	Applicant(s) CARROLL ET AL.	
	Examiner DOMINIQUE WOMACK	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 25-47 is/are pending in the application.
- 4a) Of the above claim(s) 35-42 and 44-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 25-34, and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20071002 and 20050406</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-23, 25-34, and 43, drawn to a method of treating a food.

Group II, claim(s) 35-42 and 44-47, drawn to a food product.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common technical feature of Groups I and II appears to be the method for treating a food comprising the following steps: selecting a food comprising at least one strain of culture, said stain capable of surviving a pressure treatment at a predetermined pressure and pH, and subjecting the food to a treatment pressure at or below the predetermined pressure, wherein the treatment pressure reduces, delays, prevents or eliminates growth of spoilage microflora; wherein the treatment pressure is at least 350 MPa.

3. Claim 1 of Group I is anticipated by Reps et al., Institute of Food Biotechnology, for the reasons stated in the rejection below, therefore there is no special corresponding technical feature among the claim groups of the claimed invention because the corresponding technical feature is not found to define a contribution over the prior art. Furthermore, there is lack of unity of invention and a restriction requirement is proper.

4. During a telephone conversation with David Buckingham on 19 March 2009 a provisional election was made without traverse to prosecute the invention of Group I,

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claims 1-23, 25-34, and 43. Affirmation of this election must be made by applicant in replying to this Office action. Claims 35-42 and 44-47 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

7. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

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commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Claims 13, 16, and 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

10. Regarding claim 13, its in unclear if the recitation "HN019 AGAL deposit number NM97/09513 dated 18 August 1997" denotes a trademark or trade name.

11. Regarding claim 16, its in unclear if the recitation "HN017 AGAL deposit number NM97/09515 dated 18 August 1997" denotes a trademark or trade name.

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12. Regarding claims 22 and 23, its in unclear if the recitations "HN017 AGAL deposit number NM97/09515 dated 18 August 1997" and "HN019 AGAL deposit number NM97/09513 dated 18 August 1997" denote a trademark or trade name.

13. Claim 22 provides for the use of at least one bacterial strain in a food, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

14. Claim 22 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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16. **Claims 1-9, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Reps et al. Institute of Food Biotechnology, 2001.**

17. **Regarding claims 1-2, 6-9, and 22**, Reps discloses that the pressurization of yoghurt, produced from cultured skimmed milk, containing a strain of *S. salivarius* subsp. *thermophilus* (SST), at 400 MPa for 30 min. The inactivation rate of SST bacteria was dependent on the strain and varied from 35.340 to 99.999% (pg. 132, col. 1, lines 1-33; Fig. 1). The lack of complete inactivation of some of the strains of SST is interpreted to read on the strain surviving the pressure treatment.

18. **Regarding claims 3-5**, Reps discloses that the acidified milk containing SST strain T72 had a pH between 4.0 and 4.5 (pg. 133, Fig. 3).

19. **Claims 1-2, 10, 14, 17-18, 21-22, 25, 33-34 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kortschack [US Pat No. 6,117,460].**

20. **Regarding claim 1-2, 10, 14, 17-18, 21, 22 and 33-34**, Kortschack discloses that subjecting a meat product containing Lactobacilli to a pressure between 400 to 600 MPa at 20 degrees C for 10 minutes reduces but does not completely inactivate all of the Lactobacilli (col. 6 lines 1-31). Kortschack also discloses the use of high pressure affects the 3D structure of molecules present in food. The large molecules such as proteins, enzymes, and polysaccharides are clearly more vulnerable while smaller molecules such as for instance amino acids, vitamins, and other low-molecular substances, which are of significant in respect of taste, color and nutritional value, will remain intact (col. 2 lines 5-11).

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21. **Regarding claim 43**, Kortschack disclose that high-pressure treatment is carried out when the sample is packaged in flexible sheet material (col. 1, lines 48-53).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. Claims 10 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reps et al. (Institute of Food Biotechnology, 2001) in view of Trujillo et al. (International Dairy Journal, 2000).

26. Reps et al. is relied upon as above with respect to claim 1.

27. Reps et al fails to disclose that the strain which survives is a probiotic strain.

28. Trujillo et al. discloses a method of high pressure treating yogurt samples at 100-400 MPa for 15 min at 20 degrees C (pg. 106, col. 1, section 2.2). The yogurt samples contained *L. delbrueckii* ssp. *bulgaricus* and *S. salivarius* ssp. *thermophilus* (pg. 106, col. 1, section 2.3). *L. delbrueckii* ssp. *bulgaricus* is a well known probiotic culture. Figure 1b shows that the *L. delbrueckii* ssp. *bulgaricus* in yogurt treated at 400 MPa survives. The yogurt is at a pH of 4.4 before being treated (pg. 108, sec. 3.2, lines 7-9).

29. It would have been obvious to one of ordinary skill in the art, at the time of the invention, to add *L. delbrueckii* ssp. *bulgaricus* to yogurt of Reps in order to have a yogurt containing *L. delbrueckii* ssp. *bulgaricus* after pressure treatment. One of ordinary skill in the art would be motivated to have a yogurt containing *L. delbrueckii* ssp. *bulgaricus* after pressure treatment because such a yogurt would provide probiotic benefits to its consumer.

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30. Claims 11-13, 15-16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kortschack [US Pat No. 6,117,460] in view of Gill et al. [US Pat No. 6,379,663].

31. Kortschack is relied upon as above with respect to claim 10.

32. Kortschack discloses that by varying the pressure intensity, the period of treatment, and the time of treatment as dependent on the degree of maturing of the semi finished products it is possible to adjust the desirable reductions in bacilli in any desired way (col. 6, lines 7-11).

33. Kortschack fails to disclose the use of the probiotic strains claimed by applicant.

34. Gill discloses that a pure culture of *Lactobacillus acidophilus* HN017, AGAL deposit number NM97/09515 dated Aug. 18, 1997, *Lactobacillus rhamnosus* HN001, *Lactobacillus rhamnosus* HN067 or *Bifidobacterium lactis* HN019, AGAL deposit number NM97/09513 dated Aug. 18, 1997 in an immunostimulating concentration, can be combined with a physiologically acceptable excipient or diluent (col. 1, lines 54-62). These strains are immunity enhancing and physiologically acceptable (col. 2, lines 7-14). Gill discloses that preferably said physiologically acceptable excipient or diluent is a food (col. 2, lines 27-28).

35. It would have been obvious to one of ordinary skill in the art, at the time of the invention, to add the pure probiotic strains of Gill to the food product of Kortschack in order to provide a food containing probiotic cultures. One of ordinary skill in the art would be motivated to provide a food containing probiotic cultures because such foods would have immunity enhancing and physiologically acceptable properties.

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36. **Claims 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kortschack [US Pat No. 6,117,460] in view of Michiels et al. [GB 2367997].**

37. Kortschack is relied upon as above with respect to claim 1.

38. Kortschack discloses that by varying the pressure intensity, the period of treatment, and the time of treatment as dependent on the degree of maturing of the semi finished products it is possible to adjust the desirable reductions in bacilli in any desired way (col. 6, lines 7-11).

39. **Regarding claims 26-32**, Kortschack fails to disclose pressure treatments occurring during the claimed time frames.

40. Michiels relates to the killing of microorganisms with peroxidase under super atmospheric pressure (abstract). Michiels discloses that super atmospheric pressure maybe used to pasteurize or sterilize products such as foods (abstract). Michiels discloses that the level of super atmospheric pressure is between 100 and 1000MPa, and that the exposure time is between 1 second and 5 hours (claim 10).

41. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to treat the food of Kortschack for 5 minutes, 1 minute, or 1 second in order to pasteurize the food product because "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2114.05 II. In the instant case, Kortschack discloses that by varying the pressure intensity, the period of treatment, and the time of treatment as dependent on the degree of maturing of the semi finished products it is

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possible to adjust the desirable reductions in bacilli in any desired way. In addition, Michiels discloses that it is known to treat food products with super atmospheric pressure between 100 and 1000MPa for a time of 1 second to 5 hours.

Conclusion

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOMINIQUE WOMACK whose telephone number is (571) 270-7366. The examiner can normally be reached on Monday-Thursday, 9:30am-6:00pm.

43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on (571) 272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

44. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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/D. W./

Examiner, Art Unit 1794

8 May 2009

/JENNIFER MCNEIL/

Supervisory Patent Examiner, Art Unit 1794